REMARKS / ARGUMENTS

The action by the Examiner of this application, together with the cited references, has been given careful consideration. Following such consideration, claims 1 and 4 have been amended and claims 3, 5 and 6 remain unchanged. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

Claims 1 and 4 have been amended to state that the sealed container forms a "microbial barrier completely enclosing" the items therein. The claims have further been amended to state that the step of storing occurs while "simultaneously maintaining said microbial barrier completely enclosing said items therein."

As the Examiner well knows, the present invention is directed to a method for microbially deactivating items, such as medical, dental, pharmaceutical, veterinary or mortuary instruments and devices, using a liquid microbial deactivation system. Typically, the items to be deactivated are placed within a container that is placed within a deactivation chamber of a reprocessor. Following a deactivation cycle, the container is manually removed from the reprocessor. The container is then stored remote from the reprocessor in a designated storage area. In order to maintain the device in a sterile condition, the container must ***completely enclose*** the device. When needed, the container is transported to an operation site and the devices are removed and used by the appropriate personnel. This process forms a portion of a cycle known by those skilled in the art as a "sterile supply cycle." In Attachment 1, entitled "World Forum for Hospital Sterile Supply, The Sterile Supply Cycle" by Jan Huys, the author states that:

> [b]efore they are used, sterile goods are usually stored until they are needed. In order to prevent recontamination during storage, they have to be packed. This also implies that the load is to be sterilized inside its packaging. Therefore the packaging should allow for the sterilizing agent to reach the actual load. Whereas after sterilization, it should prevent that micro-organisms can reach the items inside; it should act as a microbial barrier. Packaging should guarantee sterility up to the moment a product is used. (Huys, pg. 2, "Packaging")

The present invention provides a method of microbially deactivating items in a sealable container. The present invention also provides a method of storing the deactivated items in a location remote from a reprocessor for a prolonged period of time in a sealable container that forms a microbial barrier that ***completely enclosing*** the deactivated items.

In accordance with the present invention, a container for deactivating items and storing the deactivated items therein is provided. The container includes fluid access ports that have a normally closed position and an open position. The fluid access ports are moveable to the open position by contacting the access ports with an actuating means on a reprocessor. When the container is removed from the reprocessor following a deactivation cycle, the fluid access ports move to, i.e., assume, the normally closed position to create a microbial barrier to the entry of any microbial contamination through the access ports. In this manner, the container forms a microbial barrier that ***completely encloses*** the items contained therein. The microbially isolated items remain in the container and the container, with the devices disposed therein are transported to a common storage area to be stored until the devices are needed.

It is respectfully submitted that none of the cited references teaches, suggests, or shows a method of microbially deactivating items, creating a microbial barrier that completely encloses the deactivated items, and storing the container remotely from the reprocessor as presently set forth in the claims, or the advantages thereof.

The Examiner has rejected claims 1, 3-6 under 35 U.S.C. 112, first paragraph for failing to comply with the written description requirement. The Examiner states that there is no support for the recitations of "a sealable container" and "a microbial barrier" in the original disclosure. Support for "a sealable container" and "a microbial barrier" may be found in paragraph [0089] of the original disclosure. It is therefore respectfully submitted that the Examiner now withdraw the 35 U.S.C. 112, first paragraph rejection.

The Examiner has rejected claims 4 – 6 under 35 U.S.C. 103(a) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Halstead et al. U.S. Patent Number 6,919,057. The Examiner states that "Halstead '057 discloses a method of cleaning and disinfection of devices comprising:

a) placing the items into a rack within a container having sealing members, a cavity, and a gasket assembly comprising fluid access ports in the form of slots (abstract, Figures),

b) placing the container into a reprocessor (abstract), thus engaging the ports,

c) pumping a reprocessing liquid through the slots to contact all surfaces of the device with the liquid (abstract),

d) removing the rack and container from the reprocessor (see column 11, lines 31-34), which would inherently store the items therein until removed."

Applicant respectfully disagrees with the Examiner's interpretation that the Halstead et al. '057 patent teaches the steps engaging the ports in a container when the container is placed into the reprocessor and storing the items in the rack.

A typical endoscope used in the Halstead et al. '057 apparatus is of the type shown in Attachment #2. The endoscope has a control section that is connected to an endoscope connecter by a universal cord extending from one end of the control section. Extending from another end of the control section is an insertion tube that is designed to be inserted into a patient. As shown in Attachment #3, the insertion tube is typically several feet long. As shown in FIGS. 5 and 7 of the Halstead et al. '057 patent, the control section (labeled "head 22" in Halstead et al. '057) is disposed in a head receiving container 16, 16'. The head receiving container 16, 16' contains "an outlet 80 through which a flexible tubular member of the endoscope, such as a light guide connecter cord 82 passes (FIG. 7). A light guide connector 84 is then arranged on a horizontal mesh basket 85 of the cart 12 so that their exterior surfaces are cleaned and disinfected in the reprocessor (FIG. 2)." (col. 5, lines 47 – 53). Halstead et al. '057, therefore, discloses placing a *portion of* an endoscope, i.e. the control section, into a head receiving container while placing a light guide connector in a rack, as shown in FIG. 2 of the '057 reference. The light guide connector of the Halstead et al. '057 patent is the endoscope connector that is connected to the control section by the universal cord, shown in Attachment #2. In this respect, the head receiving container of Halstead et al. '057 does not *completely enclose* the endoscope and thus is not capable of forming a microbial barrier thereabout. Thus Halstead

et al. '057 does not disclose the step of providing a sealed container that forms "a microbial barrier completely enclosing" the items in the container as stated in claims 1 and 4.

Claims 5 and 6 depend from claim 4. Thus, it is respectfully submitted that these claims are patentable over the cited references for at least the reasons set forth above in connection with claim 4.

For the foregoing reasons, claims 4 – 6 are not anticipated by Halstead et al. '057 because Halstead et al. '057 discloses placing an endoscope partially within a container and a rack. Halstead et al. '057 does not teach, suggest, or show a method of microbially deactivating items and storing the same in a sealable container forming a microbial barrier completely enclosing the items. Halstead et al. '057 also does not teach, suggest, or show a fluid access port that both engages a reprocessor *and* forms a microbial barrier around the items within a container when the container is removed from the reprocessor.

Claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Halstead et al. '057. Referring now to claim 1, Halstead et al. '057 does not teach, suggest, or show a step of "causing said fluid access ports to assume said normally closed position to form a microbial barrier." In this regard, as discussed above regarding claim 4, the container disclosed in Halstead et al. '057 is disclosed as only surrounding a portion of the endoscope. The container of the '057 patent does not contain fluid access ports that seal a container and form "a microbial barrier ***completely enclosing***" the items in the container as stated in claim 1.

Because Halstead et al. '057 does not teach a fluid access port that is operable to form a microbial barrier, Halstead et al. '057 cannot teach a step of storing the items in a container that forms a microbial barrier completely enclosing the items.

The Examiner also states that it "would have been obvious to one of ordinary skill in the art at the time the invention was made to cause the container of Halstead to assume the closed position because Halstead discloses a leak test after reprocessing to ensure an endoscope is not damaged during reprocessing (see column 12, lines 27-30)." As Applicant understands the Examiner's statement, Examiner refers to performing a leak test on the *container* disclosed in Halstead et al. '057. As can be appreciated by one skilled in the art, the leak test discussed by Halstead et al. '057 refers to performing a leak test on the *endoscope,* not on the container.

Attachment #4 discusses the process of leak testing an endoscope, as known by those skilled in the art. A leak test is typically performed on medical instruments to verify that critical electrical components **within** the endoscope are fluidly sealed from liquid external to the endoscope. A leak test consists of forcing air into a compartment, within the endoscope, wherein the electrical components are located. If the compartment is adequately sealed, the pressurized air will not escape from the compartment and the electrical components therein will not be damaged when the endoscope is submerged in liquid. In order to perform a leak test on an endoscope, an operator must make a *physical* connection to the endoscope. The port(s) to which an operator must connect would be similar to the ports shown in FIG. 7 of Halstead et al. '057, items 172, 174, 176 and 178. In this regard, Halstead et al. '057 actually teaches opening the container to gain access to the ports on an endoscope to perform a leak test on the endoscope. Performing a leak test on an endoscope requires the container to be opened to allow access to the ports on the endoscope therein. Because Halstead et al. '057 teaches opening a container to perform a leak test on the endoscope therein, Halstead et al. '057 cannot teach a step of "storing said sealed container with said items therein at a location remote from said reprocessor for a period of time while simultaneously maintaining said microbial barrier completely enclosing said items therein."

In the present application, claim 3 depends from claim 1. Thus, it is respectfully submitted that these claims are patentable over the cited references for at least the reasons set forth above in connection with claim 1.

Applicants' Response to Examiner's Arguments

The Examiner states that "the disclosed container of the prior art would inherently provide a microbial barrier" (page 6). However, the Examiner fails to explain how the container can inherently provide a microbial barrier *completely enclosing* the device when only portion of the device is disposed inside the container. As known by those skilled in the art, a microbial barrier must *completely enclosing* the items disposed therein and prevent mirco-organisms from reaching the items.

The Examiner states that the added recitation is new matter. As previously stated, support for "a sealable container" and "a microbial barrier" may be found in paragraph [0089] of the original disclosure.

The Examiner's response fails to address how a device can be partially placed in a container and still form a microbial barrier around the *entire device.* Therefore, without completely enclosing a device it is impossible to create a microbial barrier thereabout.

The Examiner appears to agree with the Applicant that only a portion of the device is disposed in the container of the Halstead et al. '057 patent. Therefore, if only a portion of the device is disposed in the Halstead et al. '057 container, a microbial barrier *can not* be formed around the *entire* device by the Halstead et al. '057 container. In other words, because the device passes through a "port" or "outlet" of the Halstead et al. '057 container, it is impossible for the container to completely *encapsulate* the entire device.

Applicant respectfully submits that the Examiner's arguments fail to respond to Applicant's arguments that the "ports" or "outlets" in the Halstead et al. '057 container *do not* engage the reprocessor. The "ports" or "outlets" that do engage the reprocessor when the rack is moved into the reprocessor are "ports" or "outlets," item 164, which are *not* located on the container of Halstead et al. '057. Therefore, Halstead et al. '057 does not disclose the steps of "placing items within a cavity in a sealable container having fluid access ports therein, said fluid access ports having a normally closed position" *and* "causing said fluid access ports in said container to engage actuating means on said reprocessor."

The Examiner states that Applicant's arguments regarding a container that forms a microbial barrier are not persuasive. However, as previously stated, the Examiner fails to explain how a microbial barrier can be formed if only a portion of the device is disposed inside the container. The container in Halstead et al. '057 exposes a portion of the endoscope to microorganisms outside of the container if stored separately from the reprocessor. Thus, Halstead et al. '057 does not teach, suggest, or show a step of "forming a microbial barrier completely enclosing said items therein."

Finally, the Examiner's arguments regarding a leak test fail to explain how a leak test of an endoscope implies that a container is in a closed position. As stated above, a leak test

is performed on an endoscope and not a container. The Examiner fails to explain why a leak test on an endoscope would lead one skilled in the art to seal a container. A leak test requires access to the endoscope by a user and would thus teach *against* sealing a container to perform a leak test.

In summary, the cited reference does not teach, suggest, or show a method for microbially deactivating items and storing the same in a sealable container forming a microbial barrier completely enclosing said items as claimed in the present application. Halstead et al. '057 does not teach, suggest, or show a step of disengaging a fluid access port to form a microbial barrier. Further, Halstead et al. '057 does not show a step of storing a container that forms a microbial barrier completely enclosing the items while simultaneously maintaining the microbial barrier completely enclosing the items therein.

In view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters that need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. ST8630US.

Respectfully submitted,

Date: **August 29, 2007**

Mark Kusner, Reg. No. 31,115

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I hereby certify that this correspondence (along with any paper referenced as being attached or enclosed) is being deposited on the below date with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

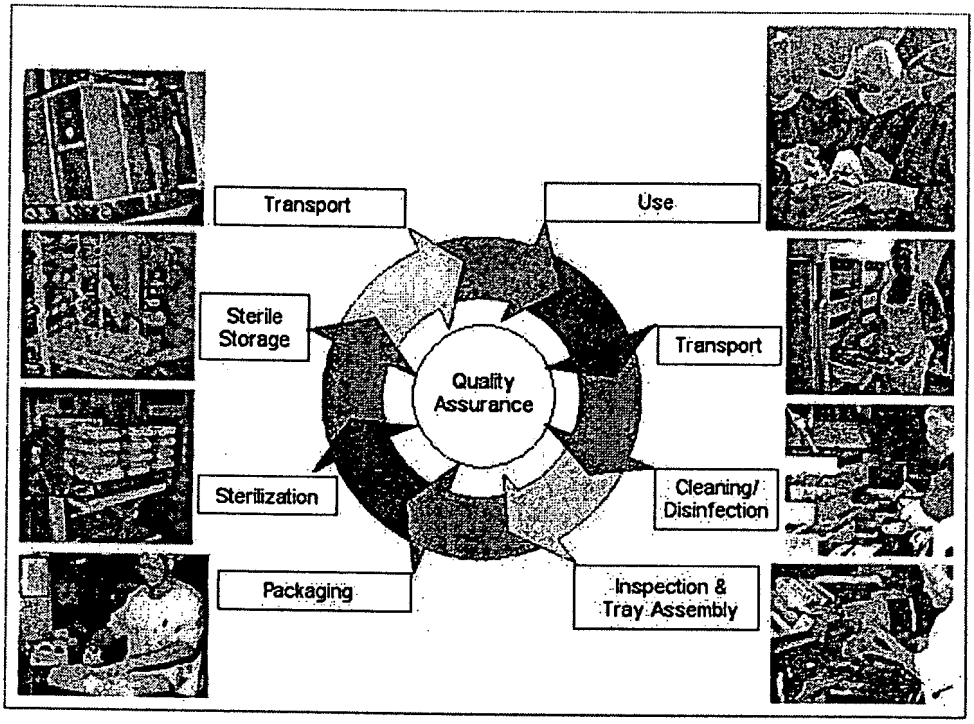
Date: **August 29, 2007**

Name: Laura K. Cahill

ATTACHMENT 1

The Sterile Supply Cycle

Author: Jan Huys



Importance of sterilization of medical supplies

More and more, infectious diseases form a serious threat to people's health. Adequate sterile supply plays an essential role in the attempt to reduce the spreading of diseases within the health service. In a number of short articles, each step in the cycle of sterile supply as it is performed in most health facilities is explained. This first article describes an overview of the sterile supply cycle. In the year to come, further descriptions of each step are worked out and will be presented by clicking on the topic title or the image of the respective step in the illustration above. Detailed information on each topic can be found in more extensive **professional literature** and the **international standards** related to sterilization.

Introduction: The cycle of sterile supply

People come to health facilities to be cured from disease and injuries. Many of their diseases are caused by micro-organisms. Therefore health facilities are places with a high incidence of disease-causing micro-organisms which are easily spread from patient to patient by the staff and equipment and other materials used for patient care. Moreover many people visiting hospitals are weak and therefore are extra susceptible for acquiring a disease. It is the task of the health facilities not only to cure diseases of its patients but also to prevent transmission of diseases from one patient to the other. An important measure against spreading of diseases is the requirement that all medical supplies, such as instruments, swabs, drapes etc, which are used on open wounds or will be in touch with the inner fluids of the body, are free of any viable micro-organisms. They have to be sterile. Some of these materials are sterilized at the factory and are designed for single use. However, many instruments and materials used for medical interventions are very expensive and are designed such that they can be re-used. A high-quality reprocessing cycle is necessary in which the used materials are treated such, that they can be used safely again. As the reprocessing of sterile goods has developed into a specialism on its own, reprocessing should centralized in a single Central Sterile Supply Department (CSSD)

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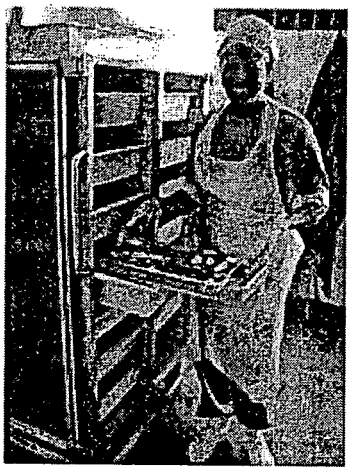
serving the whole facility. In mostly older health facilities sterilization is still decentralized. More and more the sterilization activities of these departments are put under the responsibility of a single sterilization professional in charge of sterile supply of the whole facility.



Transportation to the sterilization department

After use, for example in the operating theatre or other treatment room, the soiled materials are collected and transported in suitable containers and trolleys to the location where the reprocessing takes place: the Central Sterile Supply Department.

Cleaning

The instruments and materials are taken to the cleaning section of the sterilization department. In the cleaning section the dirty materials are handled; therefore this area is know as the 'dirty area' of the sterilization department. Cleaning implies the removal all (visible) debris and dirt. The large majority of micro-organisms including any disease-causing agents are removed here. Adequate cleaning is considered the most essential step in the reprocessing cycle of sterile goods.

[FULL ARTICLE]

Inspection and tray assembly

A missing or failing instrument while performing a surgical procedure is the annoyance of any surgeon! It can be the cause of great problems, for the patient as well as the staff performing an operation. It is therefore essential that instrument trays for all procedures are complete and that each instrument works correctly. That is why each individual instrument is subjected to a vigorous inspection, and that each tray should be double-checked for completeness.

Packaging

Before they are used, sterile goods are usually stored until they are needed. In order to prevent recontamination during storage, they have to be packed. This also implies that the load is to be sterilized inside its packaging. Therefore the packaging should allow for the sterilizing agent to reach the actual load. Whereas after sterilization, it should prevent that micro-organisms can reach the items inside; it should act as a microbial barrier. Packaging should guarantee sterility upto the moment a product is used. Poor or

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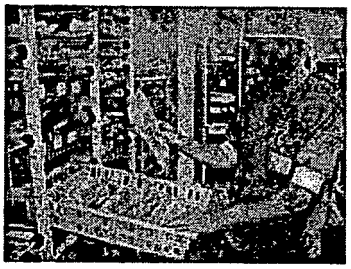
damaged packaging makes the all the work of cleaning, packaging and sterilization useless!

[FULL ARTICLE]

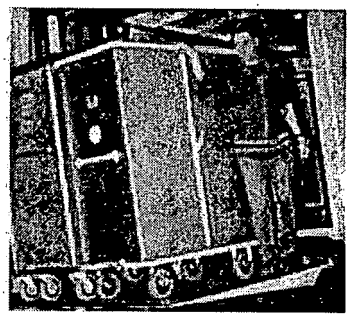
Sterilization

After packaging the load is ready to be sterilized. In a sterilizer the micro-organisms remaining after the cleaning process are killed. Their number is reduced to a probability, which is considered safe: the Sterility Assurance Level. A range of methods are in use, all with their specific field of application: **moist heat**, **dry heat**, **ethylene oxide**, **formaldehyde**, **irradiation**, and **gasplasma**. The most common and safe method used in health facilities is the sterilization by moist heat using pressurized high-temperature steam. The machines used for sterilization with steam are known as steam sterilizers or autoclaves. Sterilizers should meet the stringent technical standards for performance and safety (for example the European norm EN 285 for Large Steam Sterilizers). To ensure the safety of the staff and patients, for each sterilizer used for medical supplies, all processes in combination with each type of load in its packaging should be validated. Simply said: *You have to prove that your sterilizer sterilizes.*



Sterile Storage

Upon completion of the sterilization cycle, the goods are taken out of the sterilizer. Based on the registered process data and indicators the cycle is checked and when the required conditions are met, the load is released for storage, transport and use. The sterile goods are stored in a dedicated storage area, where they are kept until they are taken away for the next use. In a sterile storage there are special requirements for environmental conditions and stock management. A regime of product shelf life or the concept of event related sterility is used to ensure the integrity of each sterile item until its use.



Transportation to the user

When sterile goods are needed they can be requested to be picked up from the sterile storage and are transported in dedicated closed trolleys or container systems to the locations where they are needed. When materials are to be transported outside the facility, additional measures are to be taken to ensure the integrity of the materials and an adequate protocol is necessary for handing over of the goods to the end-user.

Use of sterile products

Any sterile product needs to be used correctly to ensure its safe use on a patient. By simply opening the sterile package wrongly, the instruments can be contaminated, just before they are used... By considering the concept of aseptic procedures, the chances on recontamination at the moment of using sterile goods is to be reduced to a minimum. The aseptic opening of a sterile pack and the presentation of an instrument to the surgeon are examples of such procedures.

European Committee for Standardization

International Organization for Standardization

Quality Assurance

Each step in the sterile supply cycle is crucial to a good and safe use of a sterile instrument or other item during a medical intervention. A mistake or failure in any of the steps may cause recontamination and makes the whole procedure useless. It may result in huge costs and can cause serious suffering and even endanger the life of patients and staff. That is why each step shall be subjected to vigorous monitoring. This is realized through a Quality Assurance system, in which each step in the cycle is analyzed, documented and monitored. It thus is a tool, to deliver a product that meets predefined quality standards which implies the provision of sterile supplies that are safe to use for patients and staff and perform the function they are intended for against an acceptable price.

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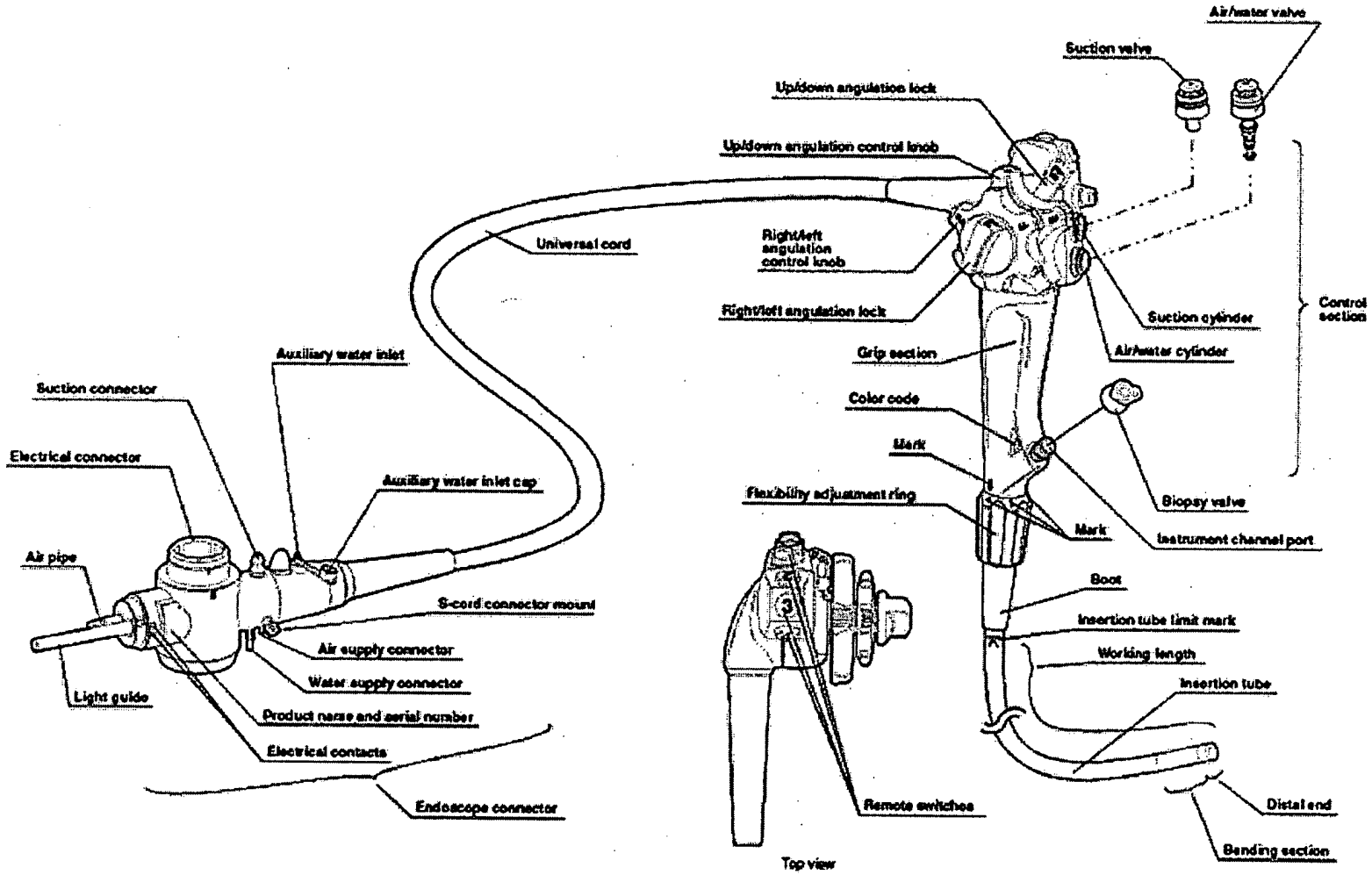
ATTACHMENT 2

Flexible Endoscopes



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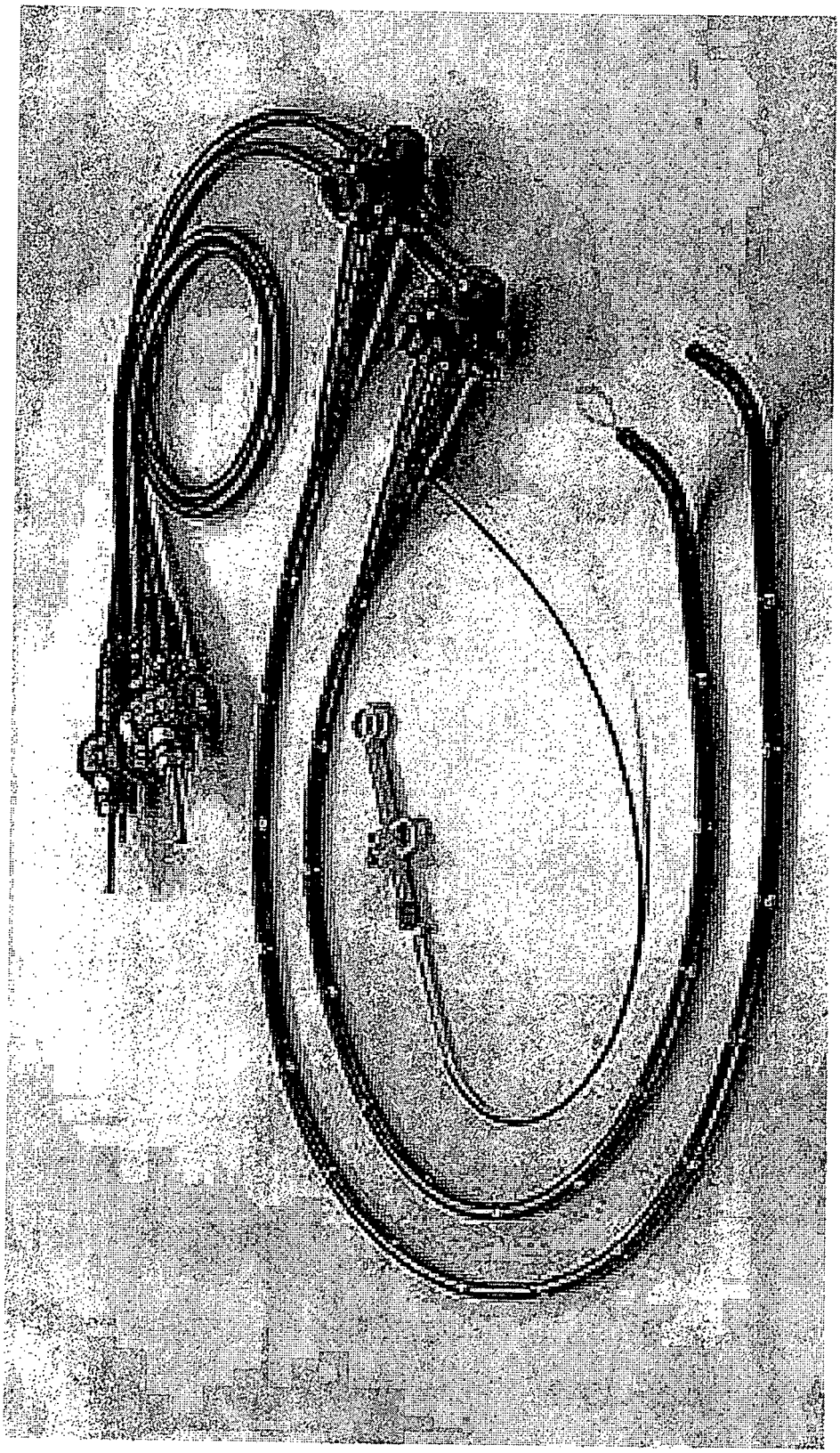
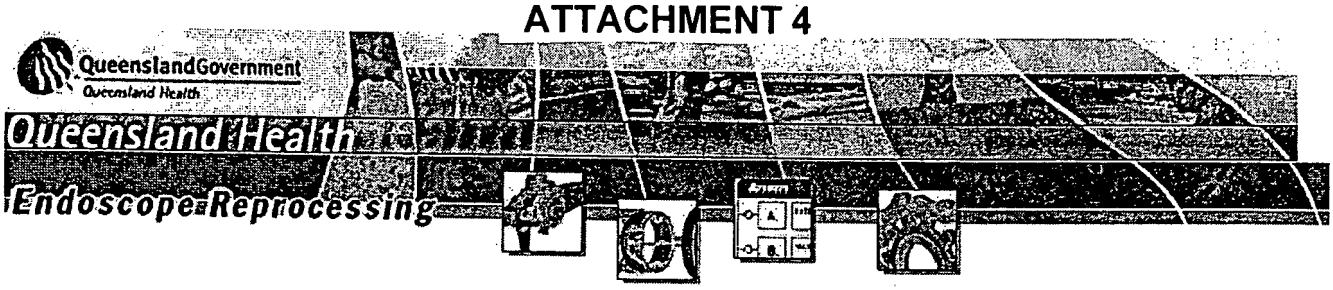
ATTACHMENT 3



ATTACHMENT 4



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Module 5

5.3 Leak testing

It is essential to leak test the endoscope according to the manufacturers instructions.

- A general outline of the procedure is provided below.
- All endoscopes should be leak tested prior to immersion and between each patient use.
- The leak test will detect damage to the interior or exterior of the endoscope.
- Perforated channels of endoscopes are an infection control risk and damage may also occur to parts of the endoscope not designed for fluid exposure.

1. Attach the leak tester and pressurise the endoscope

- Some manufacturers specify removing detachable parts prior to leak testing - others do not.

2. Immerse the endoscope in water and observe for a continuous stream of bubbles

- If the leak tester has a pressure gauge, observe for pressure loss prior to immersion (this indicates a significant leak).
- Completely immerse the entire endoscope.
- Flex the distal portion of the endoscope in all directions.
  - Flexing may help to detect a damaged section that would otherwise go unnoticed.
- Observe for a continuous stream of bubbles which indicates a leak.
- Observe the head of the endoscope, the insertion tube, distal bending section and the umbilical cable for bubbles coming from the interior of the endoscope.

Interactive

Leak Testing

3. Processing endoscopes that fail the leak test

- If a leak is detected, or the endoscope appears damaged, contact the instrument manufacturer or supplier to ascertain whether reprocessing can be undertaken without additional damage to the endoscope.

- If the endoscope fails the leak test, do not attempt to clear a blocked endoscope by blowing air under pressure through the lumen.

For more information see the section on reprocessing damaged endoscopes.

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